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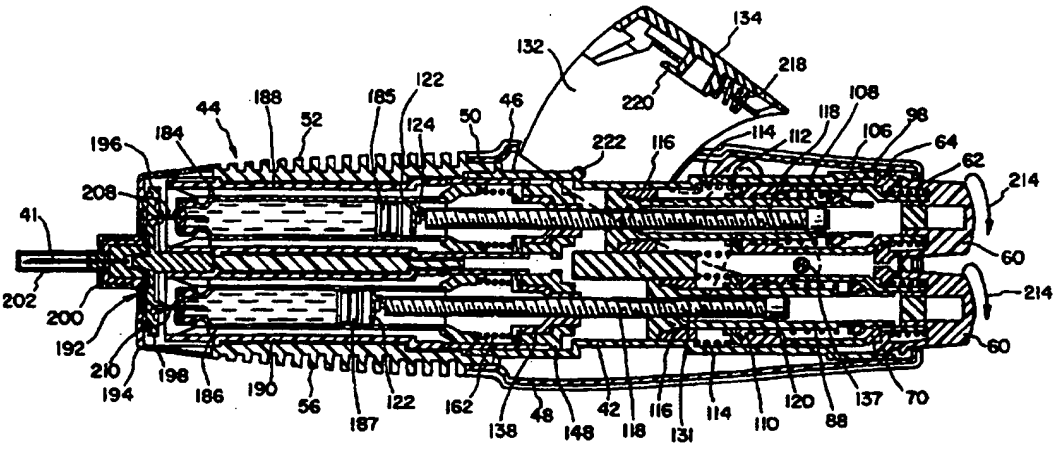

(57) Abstract

A multi-cartridge dispenser (40) for delivering two liquid medications through a single needle (41). The dispenser includes independent dual channel metering mechanisms (58), dual channel drive mechanisms (68, 88, 118, 132), and dual channel lock and pullback mechanisms (138, 148). The wing (132) must be in its "up" position for metering to take place. The wing reciprocatingly moves a driver (118) between a pre-injection position and a post-injection position to reciprocatingly advance the leadscrews (118) upon an injection stroke. The dosage indicator (66) automatically rotates to its initial zero position upon the injection stroke. The lock and pullback mechanism automatically prevents rotation of the leadscrew upon metering and injection. It also locks out the cartridge retainers (188) so that the retainers can be removed from the housing (42) only while the wing is in its "down" position. The pullback sleeve (148) unloads a pullback key (138) during a cartridge (184) change in order to enable the leadscrew to be spun freely back to its home position.

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MULTI-CARTRIDGE MEDICATION INJECTION DEVICE

This is a continuation-in-part of U.S. Application Serial No. 08/333,207, filed November 2, 1994, entitled MANIFOLD FOR INJECTION APPARATUS, and a continuation-in-part of U.S. Patent Application Serial No. 08/335,674, filed November 8, 1994, entitled MANIFOLD MEDICATION INJECTION APPARATUS AND METHOD, which is a continuation of Application Serial No. 08/041,758, now abandoned.

The present invention relates generally to devices for injecting two or more medications simultaneously and, more particularly, to a medication injection device having improved dose setting and injection capabilities.

It is medically desirable in the treatment of certain conditions of the human body to administer two or more types of medication simultaneously. The treatment of diabetes is one such example. Under certain conditions, it is desirable to simultaneously deliver two types of insulin: fast acting insulin and an intermediate acting insulin, such as isophene insulin, which takes effect more slowly but for a longer period of time. Also, a longer acting type of insulin called ultralente is available. In order to most accurately simulate the natural glucose curve of the body, the insulin user injects different ratios or combinations of these insulins several times daily.

In order to achieve such injection capability, there have been developed injection devices in which separate cartridges of a desired medication are housed. It is desirable that both medications be delivered to a patient through a single needle instead of two or more needles. Therefore, such injection devices have a manifold assembly that enables the medications to be mixed together prior to injection.

One such type of injection device is proposed in U.S. Patent No. 5,253,785. This patent asserts a dispenser for injecting variable mixed proportions of NPH and regular human insulin. The dosages of each medication are set

prior to delivery. Dosing is achieved by rotating a dose knob to translate a dosage adjuster to a retracted position. The second dosage knob is adjusted in a similar manner. The dosage adjusters are coupled to a sliding body. After the appropriate dosages are set, the sliding body is forced forwardly, which causes the drive stems to translate forwardly. Since the drive stems are connected to pistons within each medication cartridge, movement of the drive stems drives the pistons forward to expel liquid from the cartridges. The forward stroke of the sliding body is limited by the distance set by the dosage adjusters.

Another type of dual medication injection device is proposed in PCT International Application No. PCT/US93/11044. In this device, dosage knobs are rotated to translate the dosage adjusters to their retracted positions. Movement of the dosage adjusters compresses springs, which engage flanges on the adjusters. This compression preloads the drive stems so that moving the needle assembly from the predelivery position to the delivery position causes the dosages of pharmaceutical to be automatically driven from the pharmaceutical chambers, past the check valves and through the doubled ended needle cannula.

The present invention provides in one embodiment thereof a hand-held liquid medication delivery device capable of simultaneously delivering at least two medication products. The medication products are housed in variable volume containers or cartridges within the mechanism housing of the device. Each cartridge contains a liquid medication between a piston and an exit end. The medication delivery device includes independent bidirectional dosage metering mechanisms for permitting a variable dosage amount of each liquid medication to be set prior to delivery. A delivery mechanism is provided for simultaneously axially advancing piston-engaging stems to engage and axially advance the pistons in the cartridges

to effect delivery of the medications into a manifold at the distal end of the device. The medications are mixed within a valved mixing chamber in the manifold, and the mixed product is delivered through a single delivery needle extending from the manifold. A lock and pullback mechanism incorporated into the delivery device automatically prevents the cartridges from being removed from the housing while the injection actuator is in a metering or pre-injection position. The cartridges are replaced after the contents thereof have been exhausted.

In one embodiment, the present invention provides a medication delivery device having a dosage metering mechanism for setting a dosage of liquid medication to be delivered prior to injection. The dosage metering mechanism includes a knob and indicator dial which function as a single component that is rotatable with respect to the mechanism housing. The mechanism includes an indicator bearing that is locked to the housing. A torsion spring is loaded between the knob and the bearing. The knob/indicator dial is coupled to a movable element on the drive mechanism. Upon rotation of the knob to set a dosage of liquid medication to be delivered, the spring is tensed, and a dosage is indicated by a numeral on the indicator dial appearing in a window in the housing. Upon actuating the delivery mechanism, the movable element is moved out of engagement with knob/indicator dial, thereby enabling the spring to automatically rotate the indicator dial back to a zero dose position.

In one embodiment of the present invention, a multi-component medication delivery device is provided having a drive mechanism for simultaneously delivering a set dosage of each injectable product. An elongated tubular element or nut and a drive stem is associated with each liquid medication to be delivered. A driver or carrier is secured to each nut. Each driver is pivotally secured to a hand-operated actuator via side plates. Upon a single strok of the actuator from its pre-injection position to

its post-injection position, each of th drivers are simultaneously driven forwardly carrying the nut and drive stem therealong. The drive stems engage and axially advance their respective pistons to force the respective set dosages of liquid medications into the manifold and out through the delivery needle. Upon movement of the actuator back to its pre-injection position, the drive stems are moved off of their respective pistons back into a retracted position within the housing.

The present invention further provides in one form thereof a liquid medication delivery device having a lock and pullback mechanism which prevents the drive stems or leadscrews from rotating during metering and injection. This mechanism also prevents the cartridges from being changed during metering and injection. The lock and pullback mechanism includes a pullback key having an opening matching the shape of the leadscrew and being rotatable with the leadscrew, a pullback sleeve which is engageable and disengageable with the pullback key, a lock key which is rotatable with respect to the pullback sleeve, and a spring-loaded snap lock. While the actuator is in its pre-injection or dose-setting position, the lock key is locked in a first rotational position. In this first rotational position, the lock key forces the pullback key and the pullback sleeve into engagement with one another. Since the pullback sleeve is locked against rotation with respect to the housing, the pullback key and leadscrew are prevented from being able to rotate with respect to the housing. Upon injection, the drive nut engages and slightly axially advances the pullback sleeve and the lock key with respect to the housing. This moves the fingers of the lock key out of radial engagement with interfering ribs on the inner surface of the housing to enable the lock key to be rotated between a first rotational position and a second rotational position. Upon rotation of the lock key to its second position, the lock key moves slightly axially with respect to the

pullback sleeve. This permits the pullback key to becom disengaged from the pullback sleeve to allow the pullback key and leadscrew to rotate with respect to the pullback sleeve.

A cartridge retainer containing a cartridge of liquid medication is received within the nosepiece of the housing and rotatable within the nosepiece between a locked rotational position, in which the retainer cannot be removed from the nosepiece, and an unlocked rotational position in which the retainer can be removed from the nosepiece. The retainer includes tabs that are keyed for rotation with the lock key. Thus, the retainer is locked against rotation in its locked position while the actuator is in its pre-injection position, and the retainer is rotatable with the lock key to its unlocked position while the actuator is in its post-injection position, thereby enabling the retainer and spent cartridge to be removed and replaced with a new variable volume cartridge. Upon securing the new cartridge onto the housing, the piston of the new cartridge engages and axially spins the leadscrew back to its home position. This is possible since the leadscrew can rotate with respect to the housing while the actuator is in its post-injection position.

In one embodiment of the present invention, a multi-component medication delivery device is provided having a drive mechanism for simultaneously delivering a selectively set dosage of each injectable product. The device comprises a mechanism housing and a plurality of variable volume cartridges containing the medication and disposed within the housing, wherein each cartridge defines an axis of delivery of the medication from its respective cartridge. An elongated tubular element or nut and a drive stem is associated with each cartridge. A driver or carrier is secured to each nut. Each driver is pivotally secured to a hand-operated actuator via side plates. During metering, the actuator is in its "up" position, and each leadscrew is advanced a desired

distance to set a desired dosage of product to be delivered. After the desired dosages have been set, the actuator is moved in a direction transverse to the axes of delivery, toward the housing, and into its "down" position. Upon this single stroke, each of the drivers are simultaneously driven forwardly carrying the nut and drive stem therealong. The drive stems engage and axially advance their respective pistons to force the respective set dosages of liquid medications into the manifold and out through the delivery needle. As the actuator moves into its "down" position, a groove in the actuator receives a tab on the housing resulting in an audible "click" to indicate an end of dose to the user.

An advantage of the present invention is that the device enables a user to independently set each dosage of product to be delivered.

Another advantage of the present invention is that the device enables bidirectional metering of each dosage to be set.

Another advantage of the present invention is that the device is capable of indicating and locking out metering of an insufficient remaining volume of liquid medication in a cartridge.

Another advantage of the present invention is that the device provides a tactile, visual, and auditory feedback during metering.

Another advantage of the present invention is that the device provides both a visual and auditory indication of an end of dose.

Another advantage of the present invention is that the metering mechanism automatically resets upon injection, thereby eliminating the need to manually reset the indicator dial back to zero prior to subsequent metering.

Another advantage of the present invention is that metering can be achieved only while th actuator is in the

"wing up" or pre-injection position, thereby ensuring proper metering.

Another advantage of the present invention is that the device automatically prevents a user from attempting to change cartridges while the device is in its metering or pre-injection position, thereby maintaining dosing accuracy.

Another advantage of the present invention is that the leadscrew is automatically unlocked upon a cartridge change, thereby enabling the leadscrew to spin freely back to its home position upon inserting a new cartridge into the housing.

Other advantages will become apparent in the detailed description of a preferred embodiment of the invention.

Fig. 1 is a perspective view of an embodiment of a medication dispensing device in accordance with the present invention, wherein the wing is shown in its "up" position;

Fig. 2 is an exploded view of the device of Fig. 1;

Fig. 3 is an enlarged longitudinal sectional view of the medication dispensing device of Fig. 1, wherein the actuating wing is in the "up" position;

Fig. 4 is a view of Fig. 3, showing the leadscrews advanced indicating a set dosage has been established;

Fig. 5 is a view of Fig. 3, particularly showing the dispensing device immediately after an injection has taken place;

Fig. 6 is an enlarged isolated perspective view of the metering mechanism of the device of Fig. 1;

Fig. 7 is a sectional view of the engagement between the rotatable clutch member and the elongated nut;

Fig. 8 is an isolated elevational end view of the nut and the driver, particularly showing the ratchet teeth of the nut in engagement with the corresponding ratchet teeth of the driver;

Fig. 9 is a sectional view showing the externally threaded leadscrew in engagement with the internally threaded portion of the nut;

Fig. 10 is a view of Fig. 9, particularly showing the leadscrew fully advanced through the nut;

Fig. 11 is an enlarged sectional view of the assembled lock and pullback mechanism of the device of Fig. 1;

Fig. 12 is an enlarged sectional view of the lock and pullback mechanism as shown in Fig. 11, taken along line 12-12 in Fig. 11;

Fig. 13 is a sectional view of the indicator dial in engagement with the maximum dosage splines in the injection pen housing;

Fig. 14 is a sectional view of the wing mechanism of the dispensing device in engagement with the housing in its wing down position;

Fig. 15 is an exploded perspective view of the lock and pullback mechanism;

Fig. 16 is a sectional view of the assembled lock and pullback mechanism particularly showing the lock key within the groove of the pullback sleeve, thereby preventing rotation of the key with respect to the sleeve;

Fig. 17 is a view of the lock and pullback mechanism of Fig. 16, particularly showing the driver at the end of dose thereby automatically permitting rotation of the lock key with respect to the housing;

Fig. 18 is a sectional view of the interference fit between the small flanges of the lock key and the legs of the lock snap; Fig. 19 shows the legs of the lock snap in engagement with the small flanges;

Fig. 20 is a view similar to Fig. 19, showing the lock snap out of engagement with the small flanges of the lock key to permit rotation of the lock key with respect to the pullback sleeve;

Fig. 21 is a sectional view of the cartridge retainers in the distal housing of the medication

dispensing device of Fig. 1, particularly showing the retainers in an unlocked state;

Fig. 22 is a view of Fig. 21, except that the cartridge retainers have been rotated to their locked positions; and

Figs. 23A-23D are a series of elevational views of the medication dispensing device of Fig. 1 showing the manifold being removed (Fig. 23A), the cartridge retainers being unlocked and removed from the housing (Fig. 23B), new cartridge retainers being inserted into the housing (Fig. 23C) and the manifold being replaced onto the distal end of the housing (Fig. 23D).

Fig. 24A is an isolated view, in partial section, of the wing and driver mechanism of the device of Fig. 1, showing the wing in its "up" position.

Fig. 24B is a view of Fig. 24, except that the wing is in its "down" position.

In an embodiment of the invention as shown in the drawings, and in particular by referring to Figs. 1 and 2, there is shown a medication dispensing device 40 for dispensing two different liquid medications as a mixed product through a single needle 41. The injection device includes a mechanism housing 42 (Fig. 2) and a nosepiece 44. Mechanism housing 42 is contained in housing covers 46 and 48. Both mechanism housing 42 and nosepiece 44 are clear plastic materials made of ABS resins or polycarbonates. In one embodiment, mechanism housing 42 and nosepiece 44 are ultrasonically welded to one another. In one method, the mechanism housing is placed in a nest supported by the back side of the ribs of the nosepiece, and a far field weld is performed with a horn on the top of the nosepiece. In another method, the mechanism housing and nosepiece are spring loaded together, and weld energy is injected orthogonally to the pressure direction at the semicircular ribs of the nosepiece.

Mechanism housing 42 comprises two parallel tubular components 50 and 54 for housing the individual components

of device 40. Nosepiece 44 is also in the form of two parallel tubular components 52 and 56. Together, tubular components 50 and 52 form a first tubular member and tubular components 54 and 56 form a second tubular member. Although two parallel tubular members are shown in the drawings, it is possible that additional tubular members may be provided to meter and deliver three or more liquid medications from a single delivery device. Additional features of mechanism housing 42 and nosepiece 44 shall be described infra.

As shown in the drawings, dispensing device 40 contains two independent dosage metering mechanisms, a drive mechanism for simultaneously driving the pistons of the cartridges for dual medication injection, and two separate lock and pullback mechanisms. A detailed discussion of each mechanism follows. The two metering mechanisms shown in Figs 3-5 are substantially identical except for certain differences illustrated in Fig. 13. Likewise, the drive mechanism and the lock and pullback mechanisms within each tubular member are substantially identical to one another. Therefore, identical components in each of the two parallel tubular members formed by mechanism housing 42 and nosepiece 44 are given identical reference numerals.

Referring to Figs. 2-6, a dosage metering mechanism 58 is shown. Although a single metering mechanism shall be discussed herein, it is understood that delivery mechanism 40 includes two such metering mechanisms. Metering mechanism 58 comprises a knob 60, a torsion spring 62, an indicator bearing 64, an indicator dial 66, and a clutch indicator 68. Indicator bearing 64 is a thin, molded plastic annular ring with hook-shaped protrusions 70 extending radially away from its outer circumference. As shown in Fig. 3, protrusions 70 securely fit within openings 71 (Fig. 2) formed at the proximal end of mechanism housing 42. Thus, indicator bearing 64 is fixed both rotationally and axially to

mechanism housing 42. For purposes of this application, the term "proximal" shall designate a relative axial position toward the knob end of delivery mechanism 40, and the term "distal" shall designate a relative axial position toward the delivery needle end of delivery mechanism 40.

As shown in Figs. 2 and 3, indicator dial 66 is an elongate molded plastic cylinder that fits coaxially within tubular region 54 of mechanism housing 42. Knob 60 is a molded plastic cylinder with a closed proximal end and an open distal end. The proximal end of indicator dial 66 snaps into an annular groove (not shown) molded within knob 60 so that indicator dial 66 and knob 60 constitute a single rotatable component. Torsion spring 62 is coupled at one end 72 to indicator dial 66 and at the opposite end 74 to indicator bearing 64. Knob 60 and indicator dial 66 are rotated against the biasing force of torsion spring 62. In the absence of another force to retain knob 60 and indicator dial 66 in a given radial position, torsion spring 62 will return knob 60 and indicator dial 66 to a given initial rotational position, also known as the zero dose position.

As shown in Figs. 6 and 13, indicator dial 66 further includes an axially extending spline 76 which rotates within a mating slot 78 on the inside surface of tubular region 54 to confine the rotational travel of indicator dial 66 to less than 360 degrees. This serves to limit the dosage that a user can set for any single injection. In Fig. 13, there is shown an indicator dial 66′ which is identical to indicator dial 66 except that spline 76′ is of a greater width than spline 76. Thus, the maximum dosage that can be set with indicator dial 66′ is less than that which can be set with indicator dial 66.

Referring to Fig. 6, the distal portion of indicator dial 66 has a series of numerals 80 printed about the circumference thereof. An opening or window 82 in the wall of tubular region 54 and a corresponding opening 84

in housing cover 48 allows a user to view at least one of numerals 80. A lens 86 (Fig. 2) is provided in opening 84 to magnify the visible numeral 80 as desired. The numerals represent different set dosages of liquid medication to be delivered in international recognized units. As the knob 60 and indicator dial 66 are rotated, different numerals 80 appear centered in openings 82 and 84. The reference numeral "0" is present when knob 60 and indicator dial 66 are in their initial position set by torsion spring 62. The metering mechanism interfaces with the drive mechanism as discussed infra.

Referring to Fig. 2, the components of the drive mechanism are shown. The drive mechanism includes an elongated molded plastic, hollow cylindrical drive nut 88. Nut 88 includes an internally tapped bore extending therethrough. As shown in Figs. 9 and 10, the distal portion 90 of nut 88 includes internal threads 92. These threads may be any desired helix, such as a 28-45 degree helix. The remaining interior surface of the bore of nut 88 constitutes a relatively smooth surface 94. A shoulder or ledge 96 is formed at the intersection between smooth interior surface 94 and internally threaded surface 92. Referring to Fig. 7 the outer surface of nut 88 includes a plurality of axially extending splines 98 and 99. These splines engage corresponding recesses 103 and 104 in indicator clutch 68, thereby locking nut 88 to indicator clutch 68. Referring to Fig. 8, the distal end of nut 88 includes an enlarged diameter end 100 including ratchet teeth 102. Referring to Figs. 2-5, a drive spring 108 is disposed between the distal end of drive locknut 106 and the distal end 110 formed in the interior of indicator clutch 68. An indicator washer 112 is secured to indicator clutch 68, and an indicator spring 114 is disposed between washer 112 and tubular region 54 of housing 42.

An elongated metal externally threaded leadscrew 118 is adapted to threadingly engage the interior threaded

surface 92 of drive nut 88. Leadscrew 118, while generally cylindrical, has two diametrically opposite parallel flat surfaces 126 (Fig. 2) extending along its entire length. Leadscrew 118 is longer than drive nut 88, and when assembled, the proximal end of leadscrew 118 extends beyond the threaded portion of drive nut 88. The proximal end of leadscrew 118 includes an enlarged diameter portion 120. A plastic head 122 is slidably snapped onto end piece 124 of leadscrew 118. Head 122 is rotatably attached to end piece 124 and is pivotal with respect thereto.

As shown in Figs. 3-4, the metering mechanism is coupled to the drive mechanism. Specifically, ratchet teeth 67 of indicator dial 66 are in engagement with ratchet teeth 69 of indicator clutch 68. Thus, rotation of knob 60 results in rotation of indicator clutch 68. Since the splines 98, 99 of drive nut 88 are keyed to grooves 103, 104 in indicator clutch 68, rotation of indicator clutch 68 results in rotation of nut 88. Leadscrew 118 is locked against rotation during metering as shall be discussed infra. Since nut 88 is locked to the drive mechanism and cannot move axially with respect to the housing during metering, rotation of nut 88 causes axial translation of leadscrew 118 due to the threaded connection therebetween. After an initial desired dosage has been set, knob 60 may be turned either clockwise or counterclockwise to translate leadscrew 118 either forward or backward until the desired dosage is set. This allows a user to change a dosage without wasting the medication to be delivered.

Referring to Figs. 9 and 10, a carrier or driver 116 is in constant engagement with distal end 100 of drive nut 88. As shown in Figs. 2, 24A and 24B, driver 116 is secured to plates 128 which are pivotally connected to wing 132 by pins 129 being received in pivot bores 133. Wing 132 includes a plastic grip 134 which is r ceived within opening 136 within wing 132, as shown in Fig. 2.

Wing 132 includes pivot bores 135, which receive opposite ends of a pivot pin 137 which extends through opening 139 in housing mechanism 42. Bores 127 in drivers 116 receive pins 131 of side plates 128. Referring to Figs. 24A and 24B, upon movement of wing 132 toward mechanism housing 42 to its "down" position (Fig. 24B), side plates 128 and 130 are carried forwardly, which carry respective drivers 116 forwardly. Since each driver 116 is adjacent end 100 of nut 88, movement of driver 116 carries forward nut 88 and leadscrew 118. Upon movement of wing 132 away from mechanism housing 42 to its "up" position (Fig. 24A), side plates 128 and 130, driver 116, nut 88 and leadscrew 118 are all retracted.

The lock and pullback mechanism comprises a plastic molded, generally cylindrical pullback key 138 which has a proximal portion 140 including an opening 142 that corresponds to the shape of leadscrew 118 and an enlarged distal portion 144 including ratchet teeth 146. The lock and pullback mechanism further comprises a generally cylindrical molded pullback sleeve 148 comprising a proximal hollow cylindrical portion 150 and radially extending flanges 152. The outer surface of pullback sleeve 148 includes a spiral groove or track 154. The interior surface of pullback sleeve 148 including a reduced diameter inner surface 156 and an enlarged inner diameter surface (not shown). The intersection of the inner surfaces of pullback sleeve 148 form ratchet teeth 158 which are engageable with ratchet teeth 146 of pullback key 138. The lock and pullback mechanism further includes a lock key 160, a pullback spring 162, and a snap lock 164. Lock key 160 comprises a generally cylindrical portion 166 having grooved openings 168 formed at the distal end thereof and further having axially extending fingers 170 extending from the opposite end thereof. Fingers 170 include small cylindrical protrusions 172 that fit within spiral groove 154 of pullback sleeve 148. Lock

key 160 further includes ledges 174 extending radially inwardly from the inner surface of lock key 160.

Snap lock 164 comprises a cylindrical portion 176 and two axially extending legs 178 having outwardly extending tabs 180. Pullback spring 162 is disposed between inner ledge 182 of snap lock 164 and inner radially extending ledges 174 of lock key 160.

The lock and pullback mechanism performs several functions. First, pullback key 138 interfaces with leadscrew 118 to keep the leadscrew 118 from turning during metering and injection. Pullback key 138 is locked from rotation by the engagement of corresponding teeth from pullback sleeve 148 which, in turn, is constantly constrained from rotating by its interface with mechanism housing 42. Lock snap 164 and pullback spring 162 take up the variable position of the end of the glass cartridge. In addition, lock snap 164 holds the lock/pullback mechanism within the mechanism housing. Lock key 160 provides a lockout for the cartridge retainers so that the retainers can only be removed and inserted when the wing is in the "down" position. It is important to lock out cartridge change in the wing "up" position because for a proper leadscrew reset to occur, the plunger of the replacing cartridge needs to push the leadscrew back and the wing must pull the leadscrew off the plunger by a distance of at least the maximum dosing distance. Pullback sleeve 148 unloads the pullback key 138 during a cartridge change such that the leadscrew can spin freely back to its home position. The lock and pullback mechanism will be described in additional detail upon a description of the manner of use of device 40.

Referring to Fig. 2, injection device 40 includes cartridges 184, 186 disposed within cartridge retainers 188, 190. Retainers 188, 190 which may be made of a clear plastic material, such as Ektar, include internal ribs 189, 191 (Figs. 21-22) to ensure proper alignment of the cartridges in the retainers. Retainers 188, 190 are

secured within the tubular regions 52 and 56 of nosepiece 44 as discussed infra. Retainer 188 may be of a different size than retainer 190 so that retainer 188 cannot be inadvertently inserted into cylindrical tube 56, and vice versa. A manifold assembly 192 is secured to the distal end of cartridge retainers 188 and 190 and includes a front housing 194, a rear housing 196, and an elastomeric septum 198 encapsulated therebetween. The manifold assembly is described in greater detail in U.S. Patent Application Serial No. 08/333,207, filed November 2, 1994, entitled MANIFOLD FOR INJECTION APPARATUS, which disclosure is incorporated herein by reference. Needle 41 is secured to front manifold housing 194 via threaded coupling member 200. Injection device 40 further includes needle cover 202 and housing cap 204.

In order to set a dosage, wing 132 must be moved in the direction of arrow 212 to its "up" position, as shown in Fig. 3. This causes heads 122 of leadscrews 118 to be retracted out of engagement with pistons 185, 187 of cartridges 184, as shown in Fig. 3. In addition, movement of wing 132 in the direction of arrow 212 retracts clutch indicator 68 to its proximal position. While in this position, ratchet teeth 67 of indicator dial 66 are in engagement with ratchet teeth 69 of indicator clutch 68 so that rotation of knob 60 and indicator dial 66 results in corresponding rotation of indicator clutch 68. As indicator clutch 68 is rotated, internal threads 92 of clutch 68 engage with external threads 119 of leadscrew 118 to cause axial translation of leadscrew 118 toward piston 185. Leadscrew 118 is prevented from rotating due to ratchet teeth 146 of pullback key 138 being in locking engagement with ratchet teeth 158 of pullback sleeve 148. Since pullback sleeve 148 is keyed against rotation with respect to the housing, pullback key 138 and leadscrew 118 likewis cannot rotate with respect to the housing. As a result, rotation of nut 88 r sults in the nonrotational

translation of leadscrew 118 toward piston 185, as shown in Fig. 4.

Rotation of each knob 60 must initially be in the clockwise direction, as indicated by arrows 214 (Fig. 4) to set a desired dosage. Initial rotation in the counterclockwise direction is prevented by the engagement of splines 76, 76' of indicator dials 66, 66' being in engagement with dosage stops 79 formed in tubular regions 50 and 54 (Fig. 13). Once an initial dosage has been set, that dosage may be increased or decreased as desired by clockwise or counterclockwise rotation of knobs 60. Fig. 4 shows leadscrews 118 being advanced a desired axial distance with respect to their axial positions in Fig. 3, indicating that dosages have been set. Rotation of knob 60 results in corresponding numerals 80 appearing in openings 82 and 84 of housings 42 and 48, respectively, to provide a visual indication of the desired dose. In addition, rotation of nut 88 results in teeth 102 of end 100 being moved over teeth 117 of driver 116, resulting in an audible click for each incremental increase or decrease in the set dosage.

Once the desired dosage of both medications has been set, needle cover 202 is removed from needle 41, and needle 41 is inserted into the user. Wing 132 is then grasped and moved transversely towards the housing as shown by arrow 206 in Fig. 5. This results in drivers 116 moving forward which carry nuts 88 and leadscrews 118 forwardly a predetermined distance resulting in heads 122 engaging and axially advancing associated pistons 185, 187. This forces medication through cannulas 208, 210 and into manifold assembly 192 and subsequently out needle 41.

As wing 132 is pushed toward the housing, ratchet teeth 69 of clutch indicator 68 move out of engagement with ratchet teeth 67 of indicator dial 66, thereby enabling torsion spring 62 to rotate knob 60 and clutch indicator 66 to its initial rotational position, whereby the numeral zero appears through windows 82 and 84 in

housings 42 and 48, respectively. This auto zero feature permits a user to redial another dose without having to first set the metering dial to zero.

Referring to Fig. 14, grip piece 134 of wing 132 includes a downwardly extending boss portion 216 biased in a given axial position with respect to wing 132 by a spring 218. Boss 216 includes a finger 220 that slides over upstanding tab 222 on tubular region 50 and fits into place beneath tab 222 in interfering relationship therewith which holds finger 220 in place. This locks wing 132 in the "down" position at the end of dose. The engagement of finger 220 beneath tab 222 results in an audible click sound, indicating to the user that the complete dosage has been delivered. Spring 218 biases finger 220 beneath tab 222.

At the end of an injection, end 100 of nut 88 engages and axially advances pullback sleeve 148, pullback key 138 and lock key 160, as shown in Figs. 19 and 20. This moves flanges 152 of pullback sleeve 148 out of engagement with groove 149 in tubular housing region 50. This also moves protrusion 224 on lock key 160 out of interfering relationship with extension 226 of tubular region 50. Cartridge retainer 188 and lock key 160 keyed thereto can now be rotated 90 degrees to move protrusions 172 of lock key 160 within helical spline 154 of pullback sleeve 148. Such rotation moves lock key 160 and ledges 174 of lock key 160 axially away from pullback key 138 so that ledges 174 no longer engage pullback key 138. This causes ratchet teeth 146 of pullback key 138 to become disengaged from ratchet teeth 158 of pullback sleeve 148, thereby enabling pullback key 138 and hence leadscrew 118 to rotate with respect to pullback sleeve 148 and mechanism housing 42.

As shown in Figs. 20 and 21, the inner surfaces of tubular regions 52 and 56 of nosepiece 44 are specially configured restrict cartridge retainers 188, 190 to a particular radial orientation therewithin. Specifically,

keyed portions 228, 230 of retainers 188, 190, respectively, rotate within grooves 232, 234 formed in the proximal end of nosepiece 44. Each groove 232, 234 extends for 90 degrees about the circumference of the openings in nosepiece 44, thereby limiting rotation of retainers 188, 190 to 90 degrees within nosepiece 44. In addition, retainers 188, 190 can be removed from nosepiece 44 only in a particular radial orientation. Referring to Fig. 21, retainers 188, 190 are shown in their unlocked radial positions. In Fig. 22, retainers 188, 190 have been rotated 90 degrees counterclockwise in the direction of arrows 236 to cause the top edge surfaces of keyed portions 228, 230 to be in engagement with interfering internal threads 238, 240, respectively, thereby preventing the retainers 188, 190 from being axially removed from nosepiece 44. Thus, retainers 188, 190 are shown in their locked radial positions in Fig. 22.

Referring to Fig. 10, an insufficient dose remaining feature is shown. In particular, if a user dials up a dosage greater than that remaining in its cartridge, enlarged portion 120 of leadscrew 118 engages ledge 96 of internally threaded nut 88. This provides an interference stop that prevents leadscrew 118 from being translated any further. This indicates to the user that there is an insufficient dosage remaining in the cartridge. At this point, the user may choose to inject the dosage already set and then dial up the difference after inserting a new cartridge.

The process for changing a spent cartridge is illustrated in Figs. 23A-23D. It will be appreciated that the process of changing cartridges can occur only while wing 132 is in its "down" position. First, manifold 192 is removed from cartridge retainers 188, 190 and from the distal end of nosepiece 44, as shown in Fig. 23A. Next, retainers 188, 190 are rotated 90 degrees as indicated by arrow 242, and then removed. The spent cartridges are then removed from the retainers, and new cartridges are

inserted therein. Retainers 188, 190 are then inserted back into nosepiece 44, as shown in Fig. 23C. The pistons of the new cartridges engage heads 122 of leadscrews 118 and force leadscrews to rotate as indicated by arrows 244 in Fig. 23C. Leadscrews 118 are spun back to their home positions. Once keyed portions 228, 230 of retainers 188, 190, respectively, are fully seated within respective lock keys 160, retainers 188, 190 are rotated to lock them into place. Finally, manifold 192 is inserted back onto the distal end of nosepiece 44 over retainers 188, 190, as shown in Fig. 23D.

In order to make a subsequent injection, wing 132 must be moved to its "up" position (Figs. 1, 24A) in the direction of arrow 212, as shown in Fig. 3. This is necessary in order to cause ratchet teeth 69 of clutch indicator 68 to engage ratchet teeth 67 of indicator dial 66 so that rotation of knob 60 results in rotation of nut 88.

It will be appreciated that the foregoing is presented by way of illustration only, and not by way of any limitation, and that various alternatives and modifications may be made to the illustrated embodiment without departing from the spirit and scope of the invention.

CLAIMS

1. An apparatus (40) for the delivery of an injectable product, characterized by a housing (42); a container (184) mounted to said housing and including a piston (185), an exit and an injectable product between said piston and said exit; a drive stem (118) disposed in said housing and engageable with said piston; a tubular element (88) coupled to said drive stem such that said tubular element is rotatable with respect to said drive stem, wherein relative rotation between said tubular element and said drive stem controls the amount of telescopic extension of said drive stem from said tubular element to establish a set dosage of injectable product to be delivered, wherein a first coupling element (68) is secured to said tubular element for rotation with said tubular element; a drive assembly (68, 88, 118, 132) secured to said tubular element and movable with respect to said housing between a pre-injection position and a post-injection position for axially moving said drive stem with respect to said housing, to drive said piston within said container upon movement of said drive assembly from said pre-injection position to said post-injection position; and a user-engageable dose setting assembly (58) including a second coupling element (66) engageable with said first coupling element for rotation with said first coupling element to enable a user to effect said relative rotation between said tubular element and said drive stem, wherein said first coupling element is in engagement with and rotatable with said second coupling element while said drive assembly is in said pre-injection position, and said first coupling element is axially spaced from said second coupling element while said drive assembly is in said post-injection position, thereby preventing a user from setting a dose while said drive assembly is in its post-injection position.

2. An apparatus (40) for the delivery of an injectable product, characterized by a housing (42); a

container (184) mounted to said housing and including a piston (185), an exit and an injectable product between said piston and said exit; an internally threaded nut (88) disposed in said housing and rotatable with respect to said housing, and an externally threaded leadscrew (118) disposed in said nut and drivingly coupled to said piston; means (138) secured to said leadscrew for restraining said leadscrew against rotation upon rotation of said nut so that rotation of said nut causes translation of said leadscrew; a drive assembly (68, 88, 118, 132) mounted to said housing and axially movable in said housing between a pre-injection position and a post-injection position for moving said leadscrew to drive said piston within said container, said drive assembly including a clutch element (68) secured to said nut for rotation therewith, said clutch element including a first ratchet element (69), said clutch element, nut, and leadscrew being axially movable between said pre-injection position and said post-injection position; and a dose setting assembly (58) coupled to said drive assembly and comprising a rotatable element (66) having a dose setting knob (60) and a rotatable second ratchet element (67) engageable with said first ratchet element while said drive assembly is in said pre-injection position so that rotation of said knob results in rotation of said nut, said rotatable element being rotatable against the force of a spring (62) from an initial radial position to a selective final radial position for selectively advancing said leadscrew to set the dosage of injectable product to be delivered, said first ratchet element being spaced from said second ratchet element while said drive assembly is in said post-injection position, whereby said spring biases said rotatable element from said final radial position to said initial radial position upon movement of said drive assembly from said pre-injection position to said post-injection position.

3. An apparatus (40) for the delivery of an injectable product, characterized by a housing (42); a container (184) received in said housing and including a piston (185), an exit and an injectable product between said piston and said exit; a drive stem (118) disposed in said housing and drivingly coupled to said piston; and a drive assembly (68, 88, 118, 132) mounted to said housing and axially movable in said housing for moving said drive stem to drive said piston within said container; wherein a locking mechanism (138) is engageable with said drive stem and configured to restrict rotation of said drive stem with respect to said housing, said locking mechanism being in engagement with said drive stem while said container is securely mounted in said housing to prevent rotation of said drive stem with respect to said housing, said locking mechanism being automatically disengaged from said drive stem upon removal of said container from said housing, thereby permitting said drive stem to be rotated with respect to said housing.

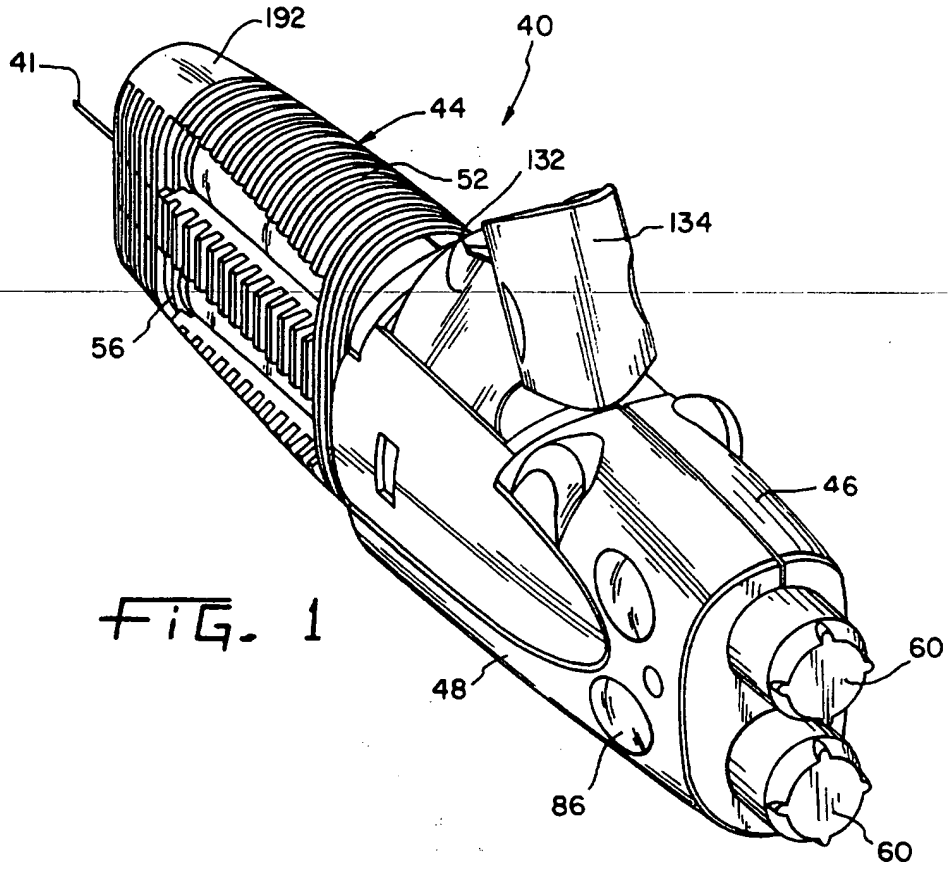

FIG. 1

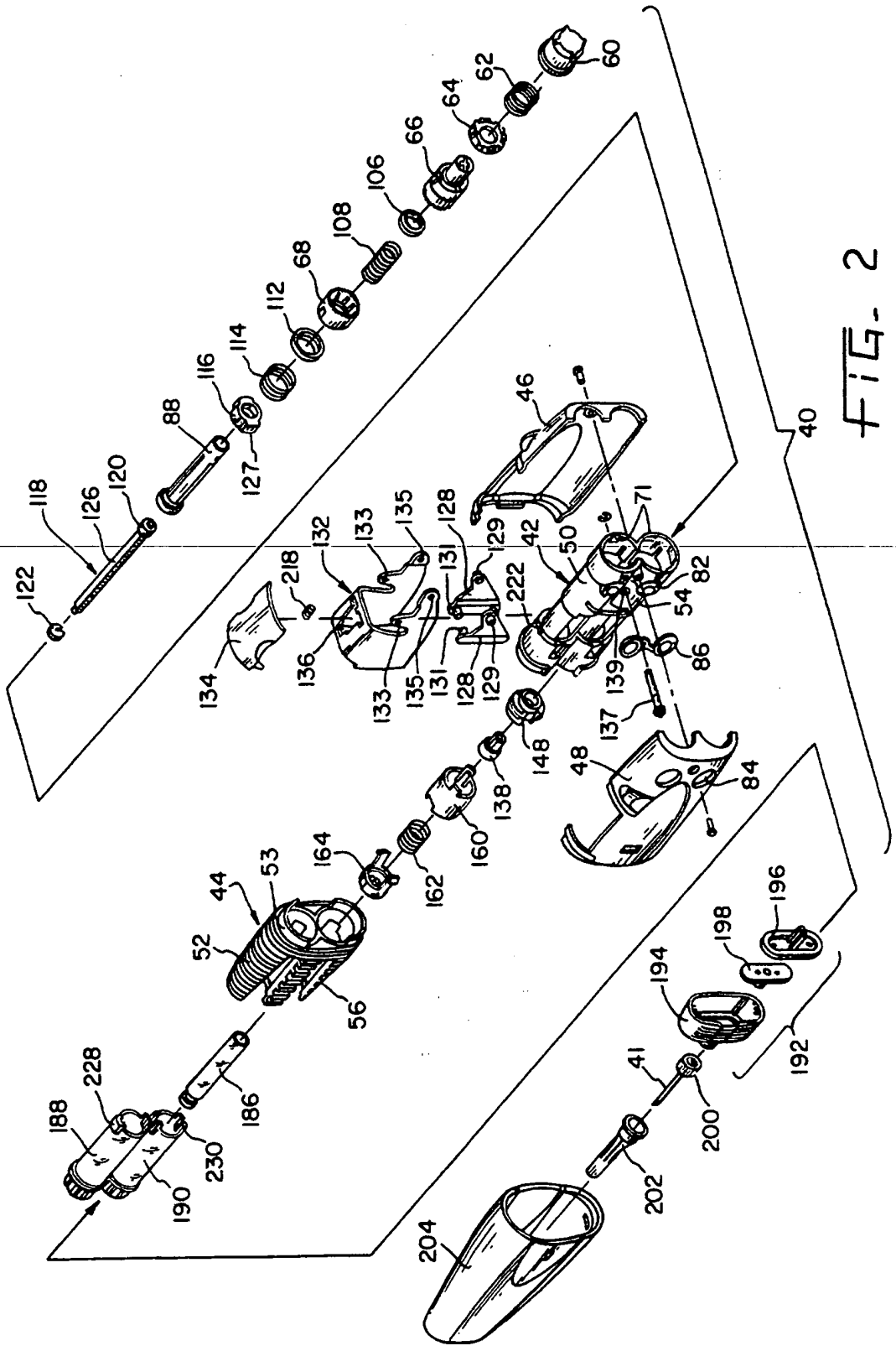
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FIG. 2

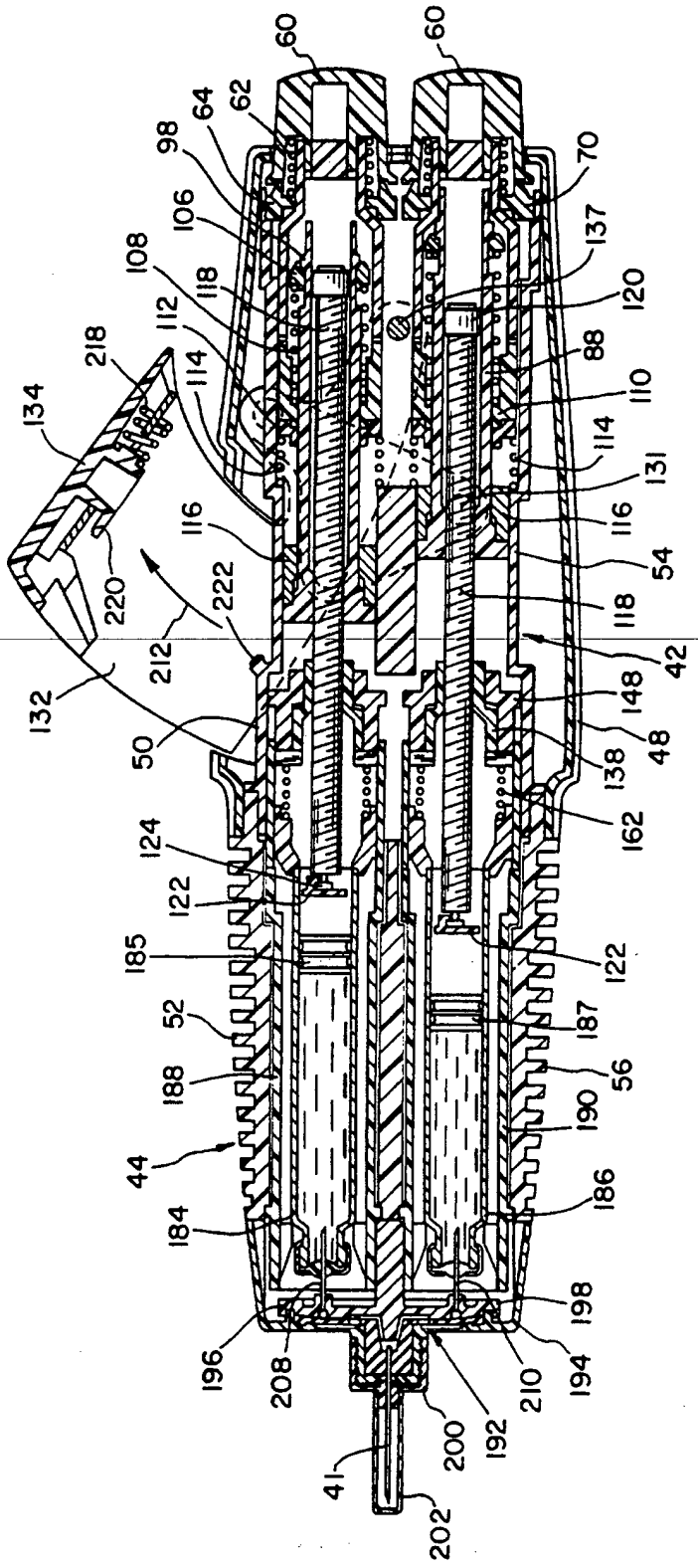
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FIG. 3

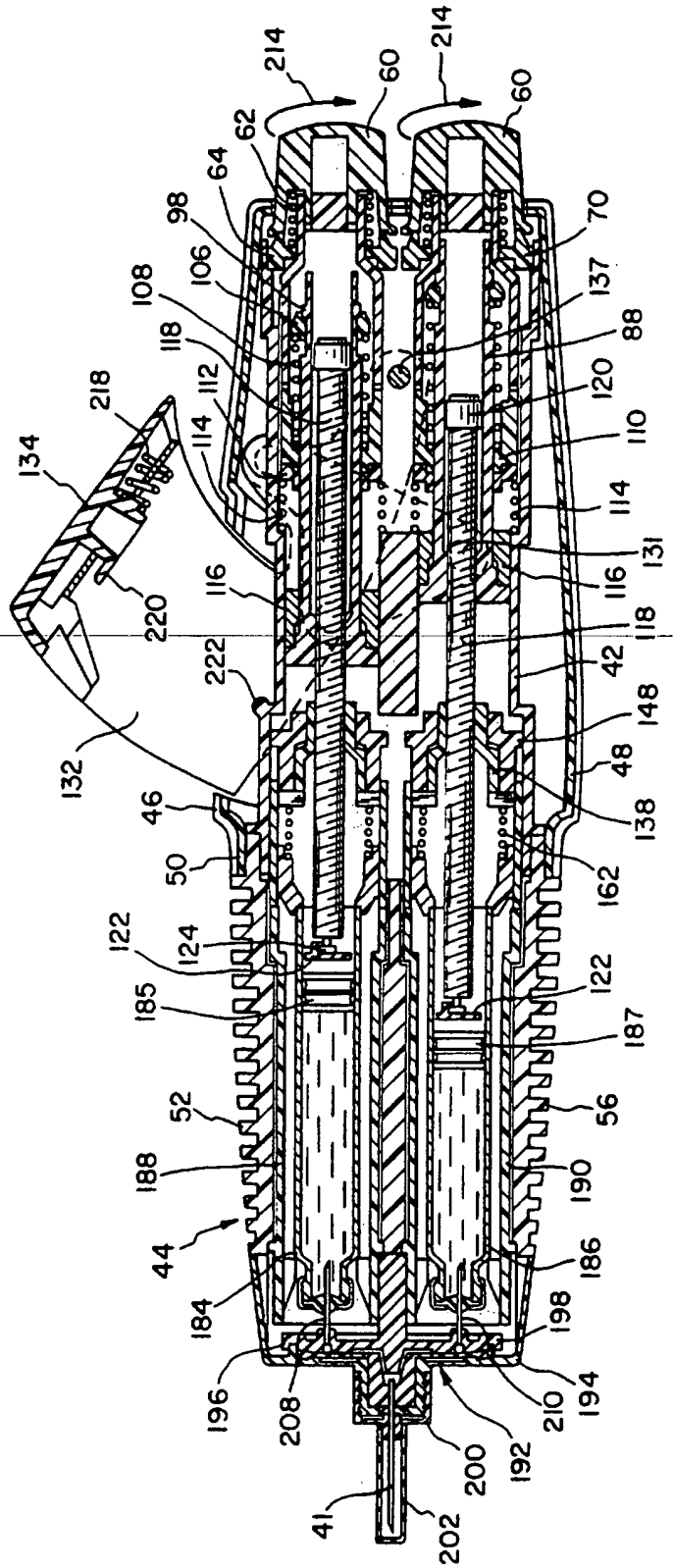
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FIG. 4

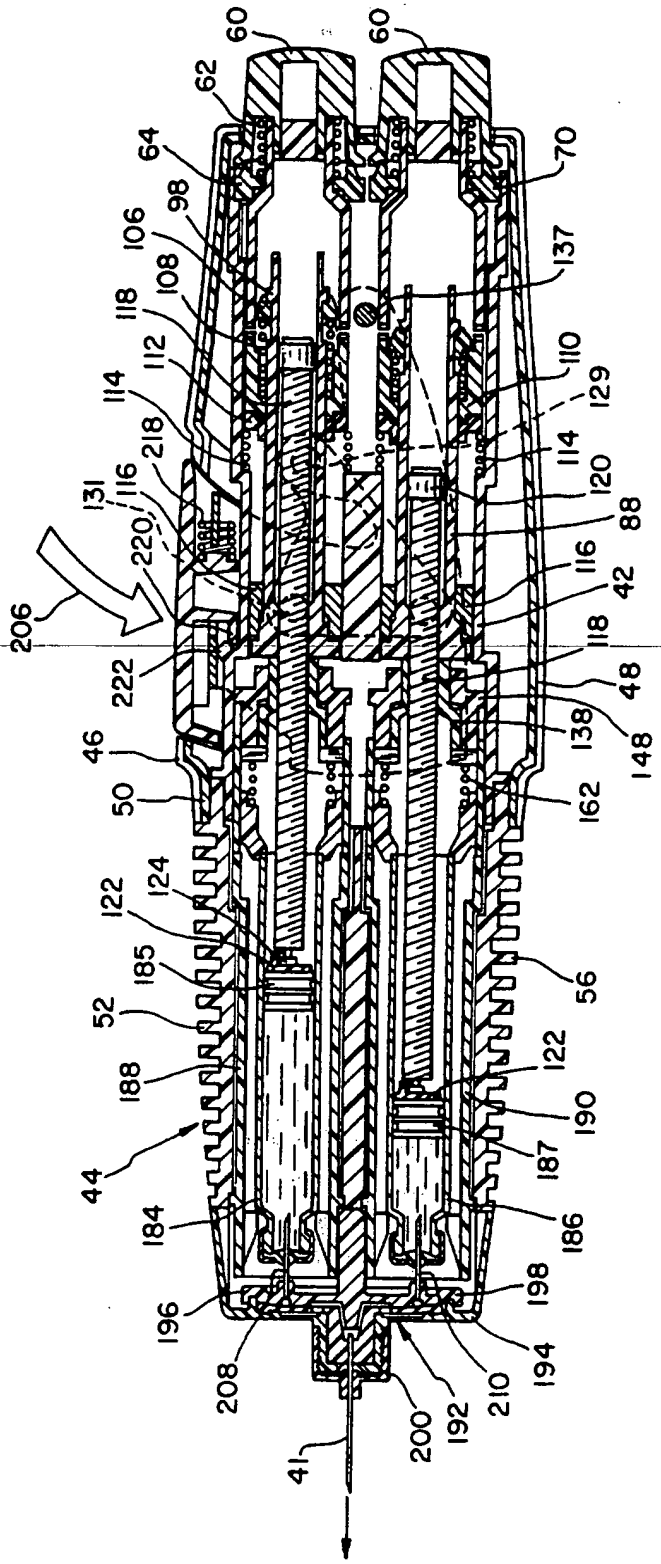
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FIG. 5

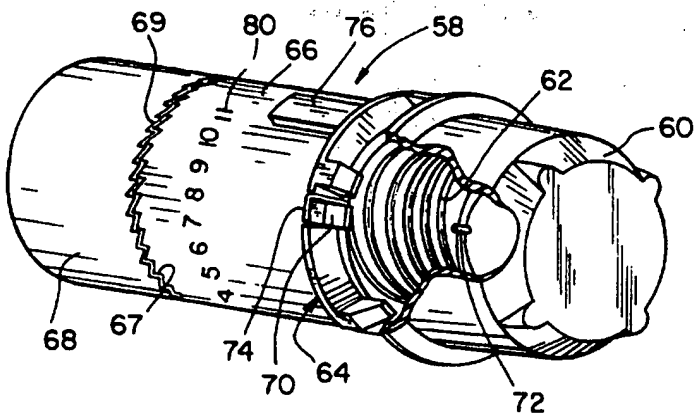

FIG. 6

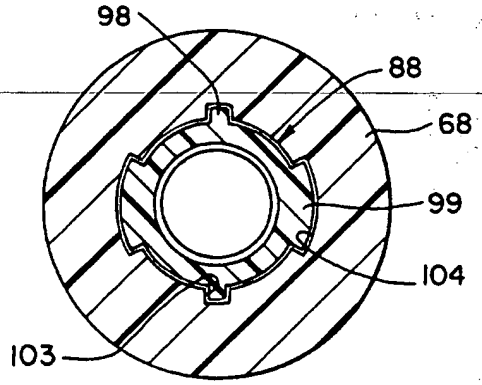

FIG. 7

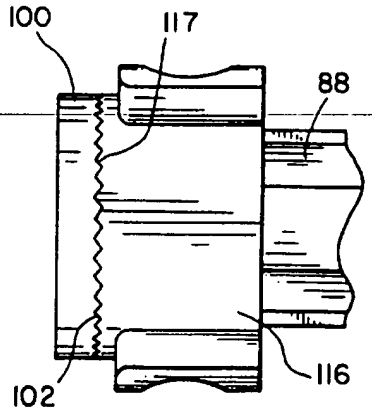

FIG. 8

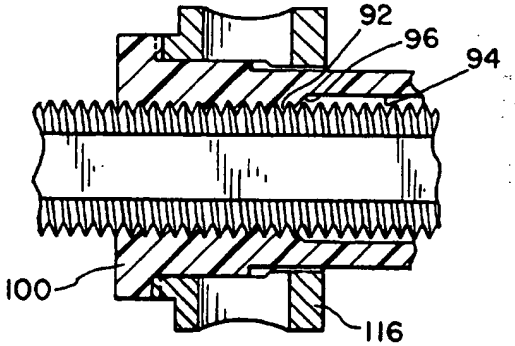

FIG. 9

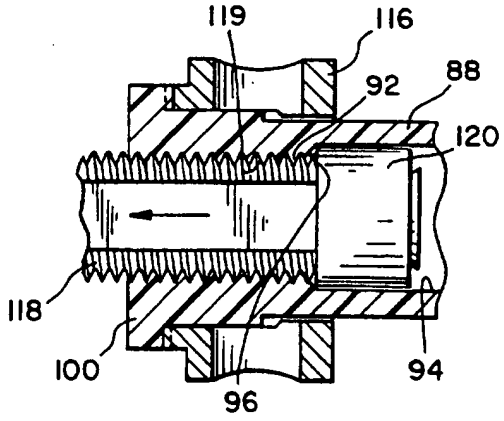

FIG. 10

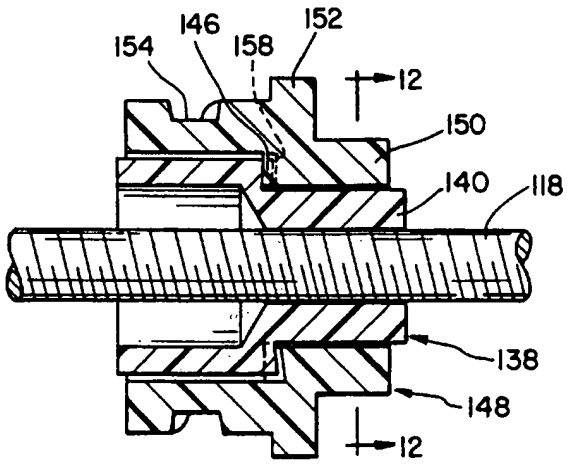

FIG. 11

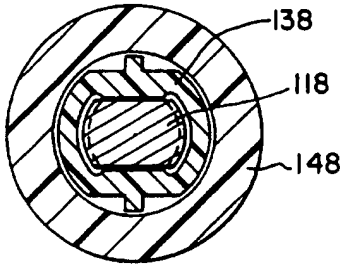

FIG. 12

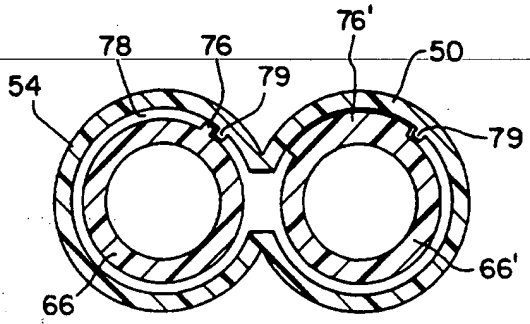

FIG. 13

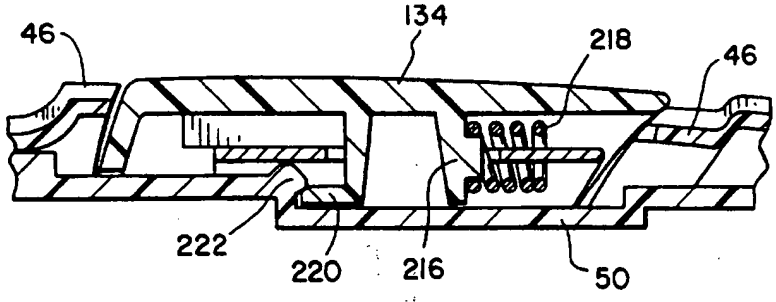

FIG. 14

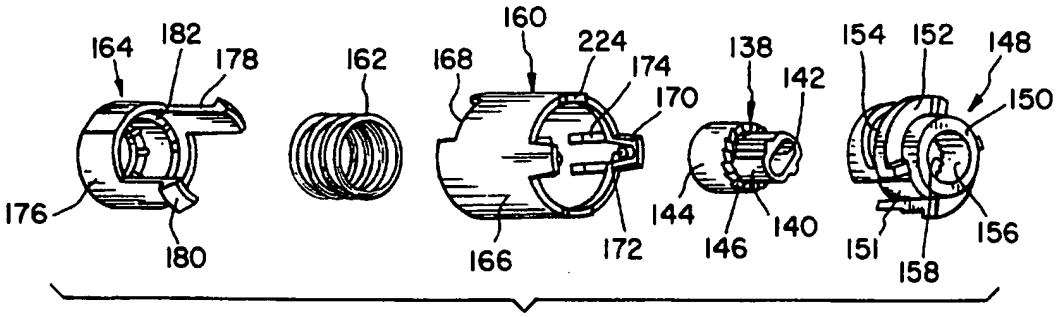

FIG. 15

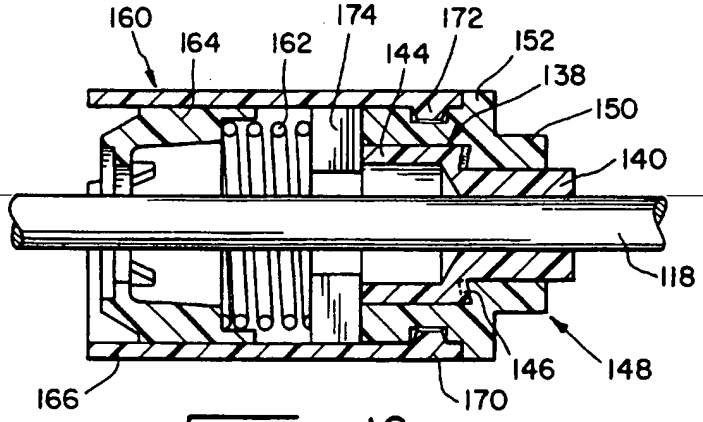

FIG. 16

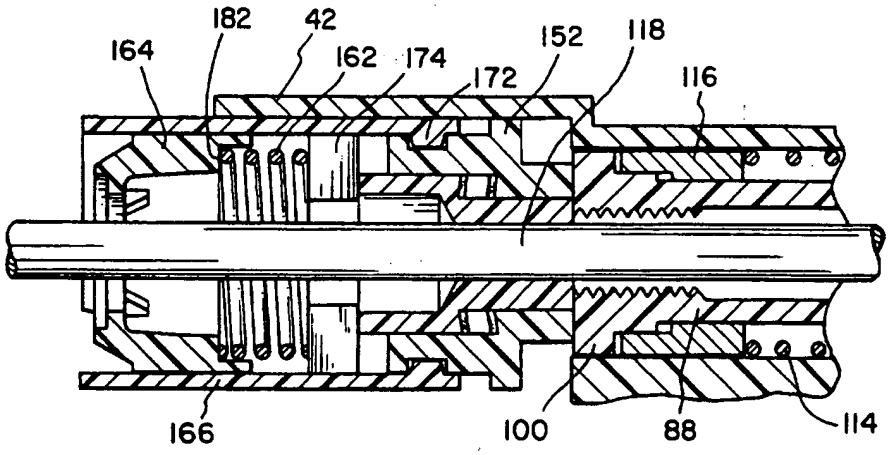

FIG. 17

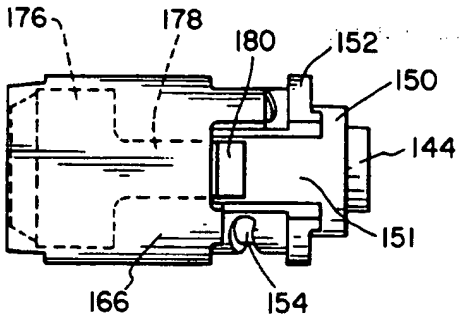

FIG. 18

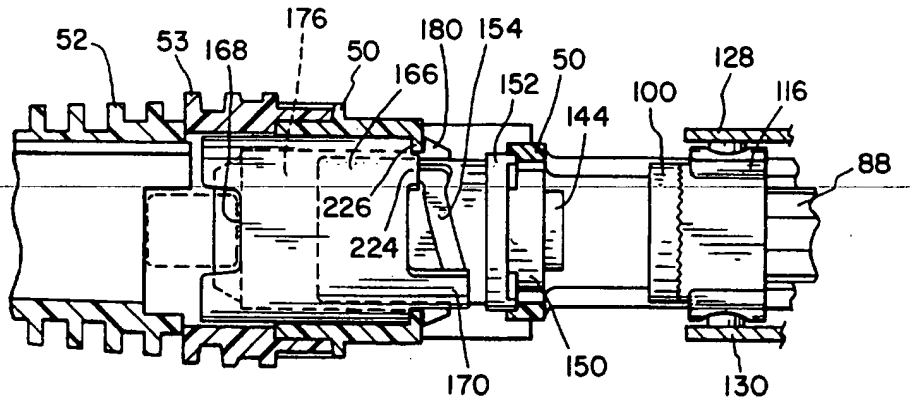

FIG. 19

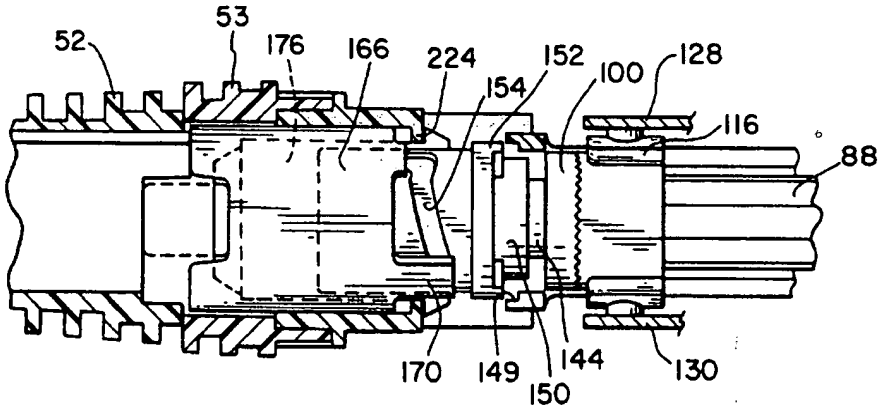

FIG. 20

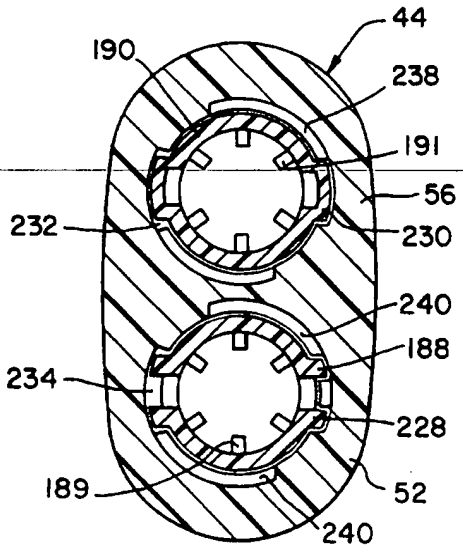
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FIG. 21

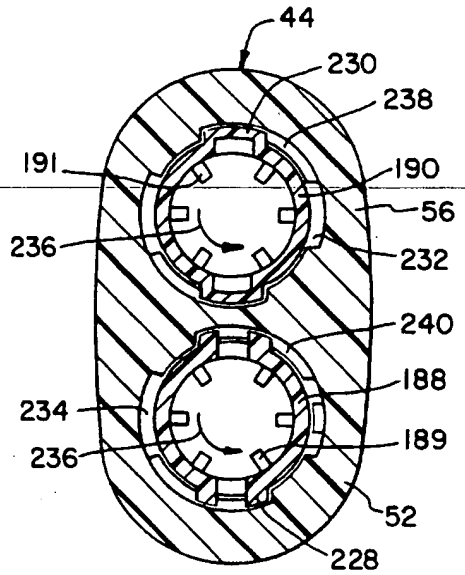
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FIG. 22

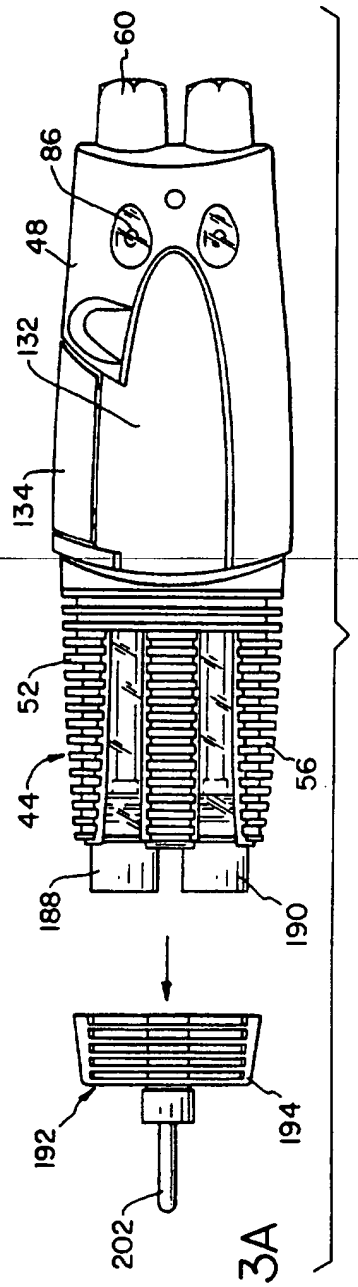

FIG. 23A

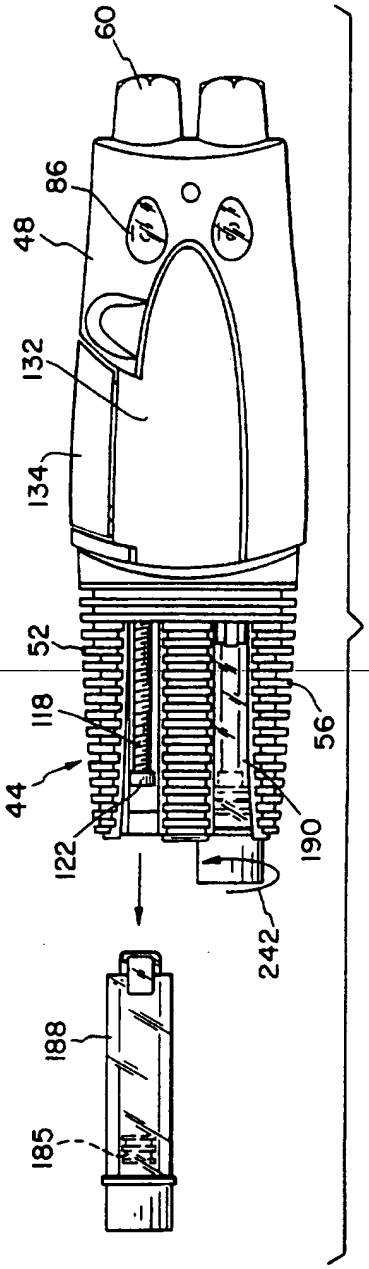

FIG. 23B

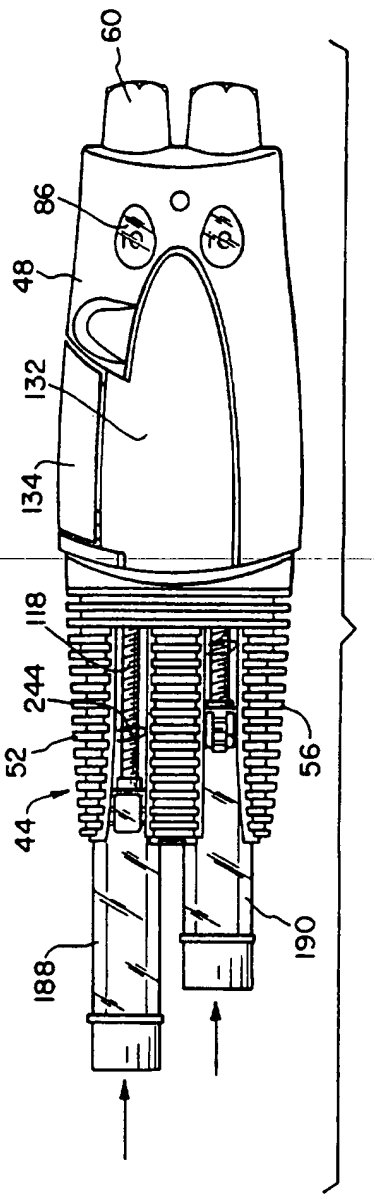

FIG. 23C

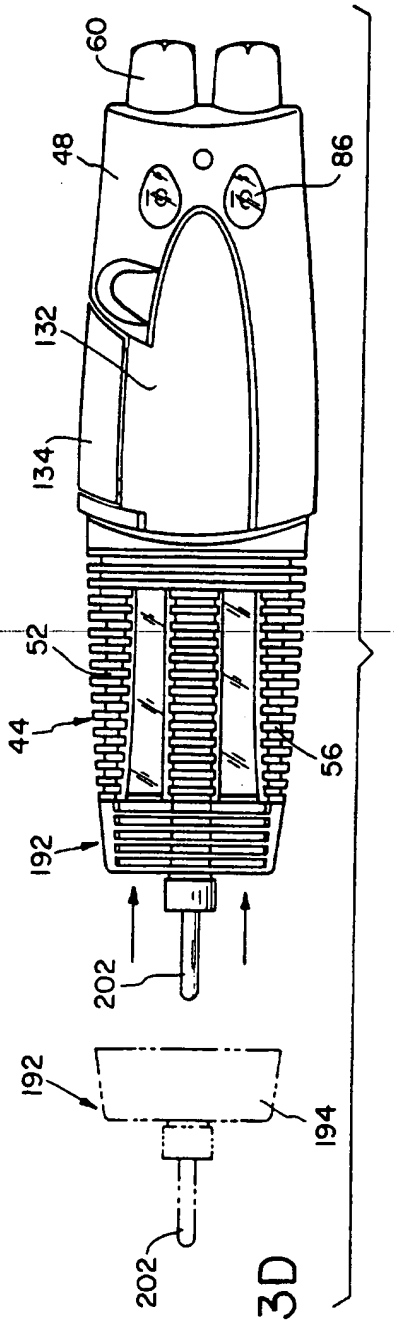

FIG. 23D

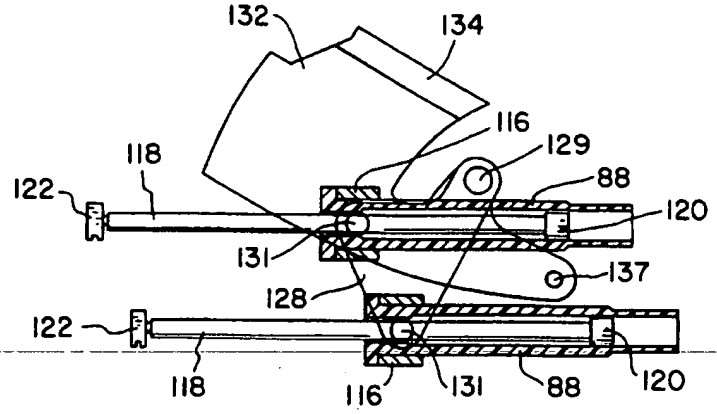

FIG. 24A

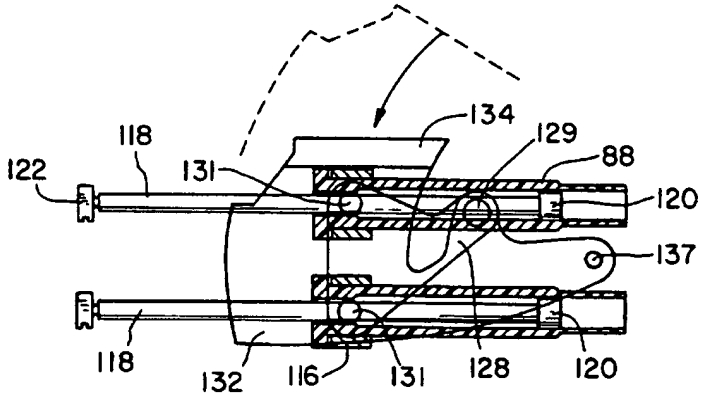

FIG. 24B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/05367

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 5/00
US CL :604/51, 83, 135, 186, 191, 211
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/51, 83, 125, 186, 191, 211

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,240,146 (SMEDLEY ET AL.) 31 August 1993, see entire reference.	1-3
A	US, A, 5,378,233 (HABER ET AL.) 03 January 1995, see entire reference.	1-3
A	US, A, 4,689,042 (SARNOFF ET AL.) 25 August 1987, see entire reference.	1-3
A	US, A, 5,112,317 (MICHEL) 12 May 1992, see entire reference.	1-3

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 12 JUNE 1996	Date of mailing of the international search report 12 JUL 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PERRY E. VAN OVER Telephone No. (703) 308-2911

Form PCT/ISA/210 (second sheet)(July 1992)*